

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

ERIC A. FORSSEN

v.

ROLF J. MEHLHORN

Interference No. 103,469

Administrative Patent Judge:
Ronald H. Smith

BOX INTERFERENCE
Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231



**FORSSSEN'S REPLY IN SUPPORT OF ITS CONTINGENT
MOTION FOR JUDGMENT UNDER 37 C.F.R. § 1.633(a)
THAT MEHLHORN'S CLAIMS 51-55 ARE UNPATENTABLE**

I. Introduction

Mehlhorn's Opposition to Forssen's Contingent Motion for Judgement¹ fails to identify any distinction between the subject matter of claims 51-55 and the prior art relied upon by Forssen.²

Unable to contest Forssen's detailed element-by-element demonstration that claims 51-55 are unpatentable, Mehlhorn resorts to "interpreting" the preamble of claims 51-55. According to Mehlhorn, claims 51-55 are patentable over the prior art because "the only reasonable interpretation of the vesicle-entrapped charged species [a phrase appearing in the preamble of

¹ Mehlhorn's Opposition to Forssen's Contingent Motion for Judgment Under 37 C.F.R. § 1.633(a) That Mehlhorn's Claims 51-55 Are Unpatentable. Citations to Mehlhorn's Opp. at ____.

² See Junior Party Forssen's Contingent Motion for Judgment Under 37 C.F.R. § 1.633(a) ("Forssen's § 1.633(a) Contingent Motion") at 3; Claim Chart IV, Appendix 1; and Mayer Balley et al., Appendix 2, attached thereto.

the claims] is that they be stable, i.e., capable of retaining species" Mehlhorn's Opp. at 2.

Mehlhorn's purported interpretation, however, in no way serves to distinguish the prior art. The Nichols reference explicitly discloses liposome-entrapped drugs which are stable, i.e., capable of retaining species. Indeed, the complexes disclosed in Nichols are six times more stable than those disclosed by Mehlhorn. Mehlhorn's sole "support" for its position is a wholly conclusory and argumentative statement by its expert, Dr. Cafiso, which should be given no weight.

Mehlhorn's asserted claim interpretation is also fatally flawed because claims 51-55 are directed to methods, not "stable entrapped drug compositions." Mehlhorn's Opp. at 2. Mehlhorn cannot "interpret" method claims into composition claims.

Mehlhorn's opposition is also noteworthy for its admissions. First, Mehlhorn concedes that he is precluded from arguing the separate patentability of claims 51-55.³ Second, Mehlhorn admits that the patentability of claims 51-55 is inextricably tied to the patentability of original claims 27-50. And third, with respect to those original claims, which are the subject of Forssen's earlier § 1.633(a) motion,⁴ Mehlhorn admits that the prior art Nichols reference teaches "that a drug composition can

³ Mehlhorn's Reply to Forssen's Opposition to Mehlhorn's Contingent Motion (2) Pursuant to 37 C.F.R. § 1.633(c)(2) to Redefine the Interfering Subject Matter by Adding a Claim to be Designated as Corresponding to the Count at 2.

⁴ Junior Party Forssen's Preliminary Motion For Judgment Under 37 C.F.R. § 1.633(a).

be accumulated in the liposome." Mehlhorn's Opp. at 4; Third Cafiso Declaration at ¶ 3.

In short, it is undisputed that Mehlhorn's claimed process of pH inducement of charged chemical species into liposomes is taught by Nichols. Further, Nichols explicitly discloses liposome-entrapped drug complexes which are stable, i.e., capable of retaining species. Therefore, there can be no dispute that claims 27-50 and 51-55 are indeed unpatentable. Accordingly, both Forssen's original § 1.633(a) motion and its contingent § 1.633(a) motion regarding claims 51-55 should be granted.

II. The Prior Art Discloses "Stable" Liposome-Entrapped Drug Compositions

By a series of shifting arguments, Mehlhorn has repeatedly tried to find a way around the Nichols publication. First, Mehlhorn argued that dopamine loaded into liposomes was not a "drug." After Forssen established that the prior art taught that dopamine is a drug, Mehlhorn shifted ground and argued that Nichols does not disclose a "stable entrapped drug composition." Forssen then demonstrated that Nichols discloses "entrapped" drugs which are "stable" in liposomes.⁵

Now in a last ditch attempt to find a line between Nichols and claims 51-55, Mehlhorn argues that the claims are limited to "stable" compositions; i.e., compositions "capable of retaining species." Mehlhorn's Opp. at 2. Specifically, Mehlhorn asserts that "Forssen is wrong when it urges that stability of the

⁵ See Forssen's Reply to Mehlhorn's Opposition to Forssen's Motion for Judgment Under 37 C.F.R. § 1.633(a) at 4-7.

vesicle is not an important aspect of the invention defined by the count of the present interference and claimed by Mehlhorn." Mehlhorn's Opp. at 4.

The stability of Mehlhorn's disclosed liposome compositions, however, does not serve to distinguish them or claims 51-55 from the prior art. The prior art (Nichols) discloses liposome-entrapped drug compositions which are more stable than those disclosed by Mehlhorn. Indeed, Nichols discloses liposome-entrapped drug complexes which were stable six fold longer than those produced by Mehlhorn.⁶

Mehlhorn's sole support for the contention that the prior art does not teach stable liposome complexes is a statement by Dr. Cafiso that "I continue to believe that Mehlhorn claims 27-50 are not disclosed or suggested by Nichols and Deamer."⁷ Mehlhorn's Opp. at 4. This statement, however, is wholly conclusory and argumentative and is entitled to no weight. Thus, there is no genuine dispute that claims 51-55 are unpatentable.

III. As a Matter of Law, Mehlhorn's Method Claims Cannot be Interpreted as Claiming "Stable Entrapped Drug Compositions"

It is a fundamental tenet of patent law that the invention must be limited to that which is claimed. Environmental Designs Ltd. v. Union Oil Co. of California, 713 F.2d 693 (Fed. Cir.

⁶ Nichols discloses that the accumulated entrapped catecholamine was retained within the liposomes for at least ninety minutes, while Mehlhorn discloses the chemical species inside the liposome for only fifteen minutes after loading. Reply Declaration of J. Wylie Nichols at ¶ 7-8.

⁷ Third Declaration of David S. Cafiso, Ph.D. at ¶ 3(b).

1983), cert. denied, 464 U.S. 1043 (1984). While Mehlhorn contends "that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification" (Mehlhorn's Opp. at 2), this does not mean that Mehlhorn's method claims may now be construed as claiming "stable entrapped drug compositions." Such a rewriting of the claims is not "reasonable" and finds no support in law or fact.

Claim 27, from which claims 51-55 depend, is directed to a method of pH induced loading. It refers to the formation of liposomes (a method step) and entrapment (also a method step), not of specific drugs, but of "chemical species having one or more acid pH responsive groups."⁸ Second Declaration of Dr.

⁸ Claims 27 reads:

27. (Amended) A method of preparing a [lipid-like] liposome vesicle-entrapped charged chemical species which comprises:

(a) forming liposomes in:

(i) an aqueous medium containing an acid which is substantially impermeable through the vesicle to give an acidic liposome-containing aqueous medium in which the acid is present in the internal and external liposome phases; or

(ii) an aqueous medium containing a base which is substantially impermeable through the vesicle to give a basic liposome-containing aqueous medium in which the base is present in the internal and external liposome phases;

(b) adding:

(i) to the thus-obtained acidic liposome-containing aqueous medium a charged (continu d...)

Prestegard at ¶ 6. Since the claims "provide the concise formal definition of the invention," Autogiro Co. of Am. v. United States, 384 F.2d 391, 395 (Ct. Cl. 1967), claims 51-55 define a method, not a composition. Moreover claims cannot be broadened or narrowed by judicial interpretation to give a patentee something different from what the claims define. Id. at 396. While it is proper to construe claims in view of the specification and the state of the art, the specification may not be used to add to or detract from the claims. Cimiotti Unhairing Co. v. American Fur Ref. Co., 198 U.S. 399, 410 (1905).

Thus, while Mehlhorn contends that statements in the Mehlhorn specification show the "stability" of the species entrapped in the vesicles, the specification cannot be used to reinterpret Mehlhorn's method claims as composition claims or as claims to "stable entrapped drug compositions." See, Yale Lock Mfg. Co. v. Greenleaf, 117 U.S. 554, 559 (1886) ("The scope of letters-patent must be limited to the invention covered by the

⁸(...continued)

chemical species which is cationic or

(ii) to the thus-obtained basic liposome-containing aqueous medium a charged chemical species which is anionic, and

(c) adding to the external liposome phase:

(i) a base to thereby induce the cationic chemical species to pass into the liposomes' internal acidic aqueous phase or

(ii) an acid to thereby induce the anionic chemical species to pass into the liposomes' internal basic aqueous phase.

claim, and while the claim may be illustrated it cannot be enlarged by language used in other parts of the specification").

Accordingly, as a matter of law, Mehlhorn's claims must be limited to a method of inducing a chemical species into liposomes by means of a pH gradient. That method, as Mehlhorn admits in its Opposition, is disclosed in the prior art Nichols reference.

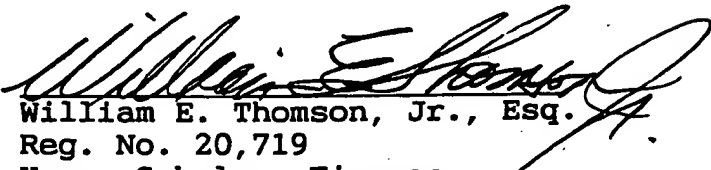
IV. Conclusion

In short, Mehlhorn's claims are directed to a method of using pH inducement to entrap chemical species, including drugs, into liposomes and no amount of argument by Mehlhorn can recast them into claims to a "stable entrapped drug composition". Mehlhorn admits that this method for accumulating drug compositions into liposomes is in the prior art through the Nichols reference. Further, the stability of the entrapped drug does not render claims 51-55 patentable. Accordingly, original claims 27-55 and new claims 51-55, whose patentability is based upon these original claims, should be found unpatentable.

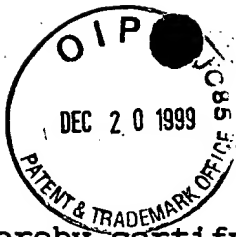
Respectfully submitted,

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Date: June 12, 1995



CERTIFICATE OF SERVICE

I hereby certify that a copy of the attached paper, "FORSSSEN'S REPLY IN SUPPORT OF ITS CONTINGENT MOTION FOR JUDGMENT UNDER 37 C.F.R. § 1.633(a) THAT MEHLHORN CLAIMS 51-55 ARE UNPATENTABLE," is being served upon the Senior Party, Rolf J. Mehlhorn, in accordance with 37 C.F.R. § 1.646 by mailing a copy of said paper, including the exhibits, this 12th day of June, 1995, via Federal Express, postage prepaid, to the lead attorney for the Senior Party at the following address:

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